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EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

NOV 27 2000

Mr. Donald V. Johnson
Director, Quality and Regulatory Affairs
New Star Lasers, Incorporated
9085 Foothills Boulevard
Roseville, California 95747

Re: New Star Model 1320 Nd: YAG
Surgical Laser, K962791, K981662

Dear Mr. Johnson:

The Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed your October 23 letter in response to our letter dated September 5. We have the following comments.

At this time, we acknowledge New Star's removal of all violative claims for the New Star Model 1320 Nd: YAG Surgical Laser from your web site while it is under construction. We would expect that New Star limit its promotion of the New Star laser to the cleared intended uses: i.e., in dermatological procedures for incision, excision, ablation, and vaporization, and coagulation of soft tissues in both printed promotional materials when the re-construction to your web site is complete.

Item 2 of your letter indicates that you are distributing journal articles with a label that reads, "Wrinkle Treatment Indication Pending FDA Clearance." We object to the use of this language on your journal reprints because your device has not been cleared by the agency for wrinkle treatment. Dissemination of journal articles with this kind of language is considered by the agency to be promotion of your laser for an uncleared use and causes your device to be misbranded and adulterated. It would, however, be acceptable to distribute such journal reprints in accordance with the agency's unsolicited request policy i.e; you may distribute journal articles that discuss an off-label use of your device if specifically requested by a consumer, physician, or other third party. New Star however, may not initiate the distribution on its own accord.

Additionally, the FDA Modernization Act of 1997, section 401, as well as 21 CFR Part 99 describes certain circumstances when the dissemination of information regarding unapproved/uncleared uses may be distributed to health care practitioners. We suggest you become familiar with these regulations which may be found on FDA's home page at the internet address: http://www.fda.gov/cdrh/devadvice/371.html.

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Please submit a prompt response to this office in writing regarding your plans for further corrective action and for ceasing distribution of the violative materials. You may submit your response to me at the letterhead address.

Sincerely yours,

Steven E. Budabin, M.S.
Consumer Safety Officer
Promotion and Advertising
Policy Staff
Office of Compliance
Center for Devices and
Radiological Health

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To:

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